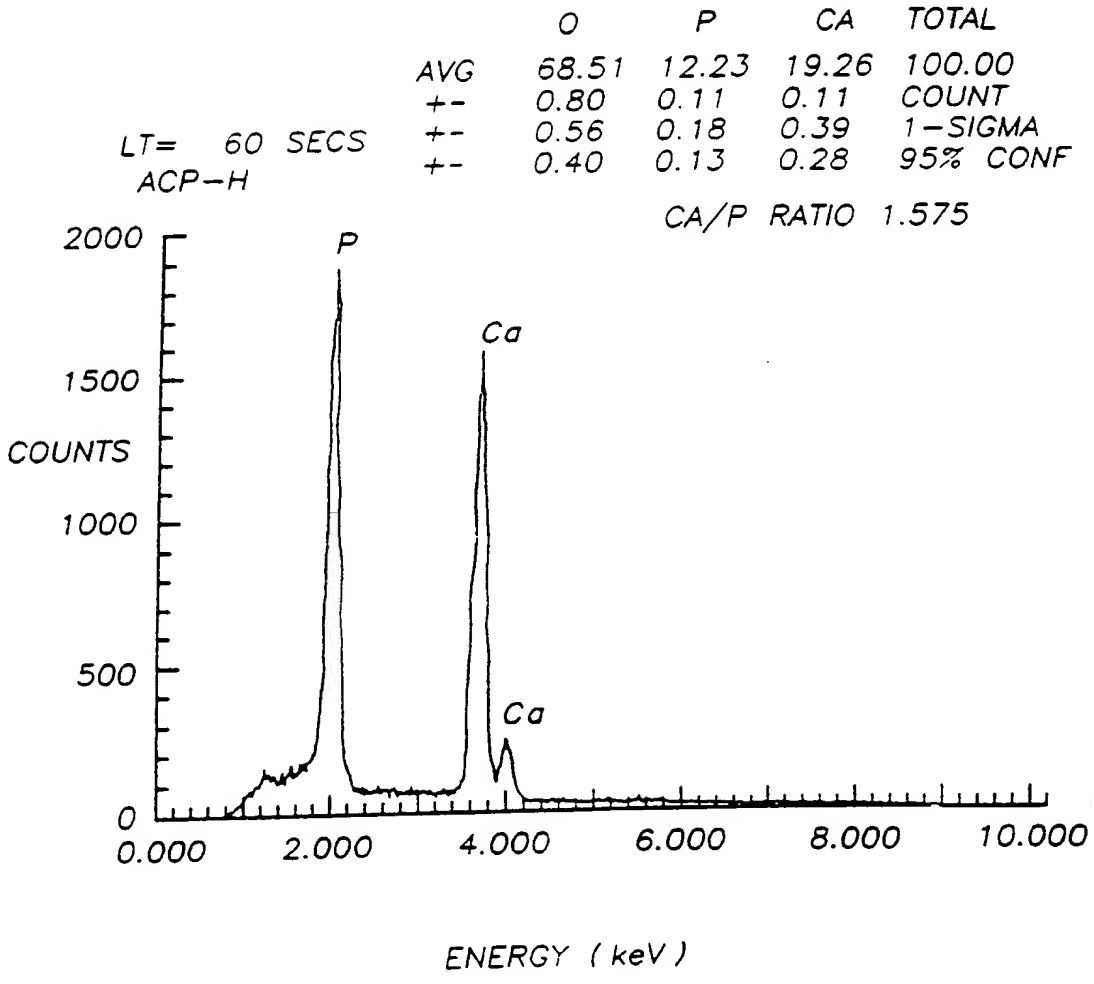
FIG. 1

FIG. 2


O P CA TOTAL
AVG 68.51 12.23 19.26 100.00
+- 0.80 0.11 0.11 COUNT
+- 0.56 0.18 0.39 1-SIGMA
+- 0.40 0.13 0.28 95% CONF
LT= 60 SECS
ACP-H
CA/P RATIO 1.575
2000
1500
1000
500
0
COUNTS
P
Ca
Ca
0.000
2.000
4.000
6.000
8.000
10.000
ENERGY (keV)

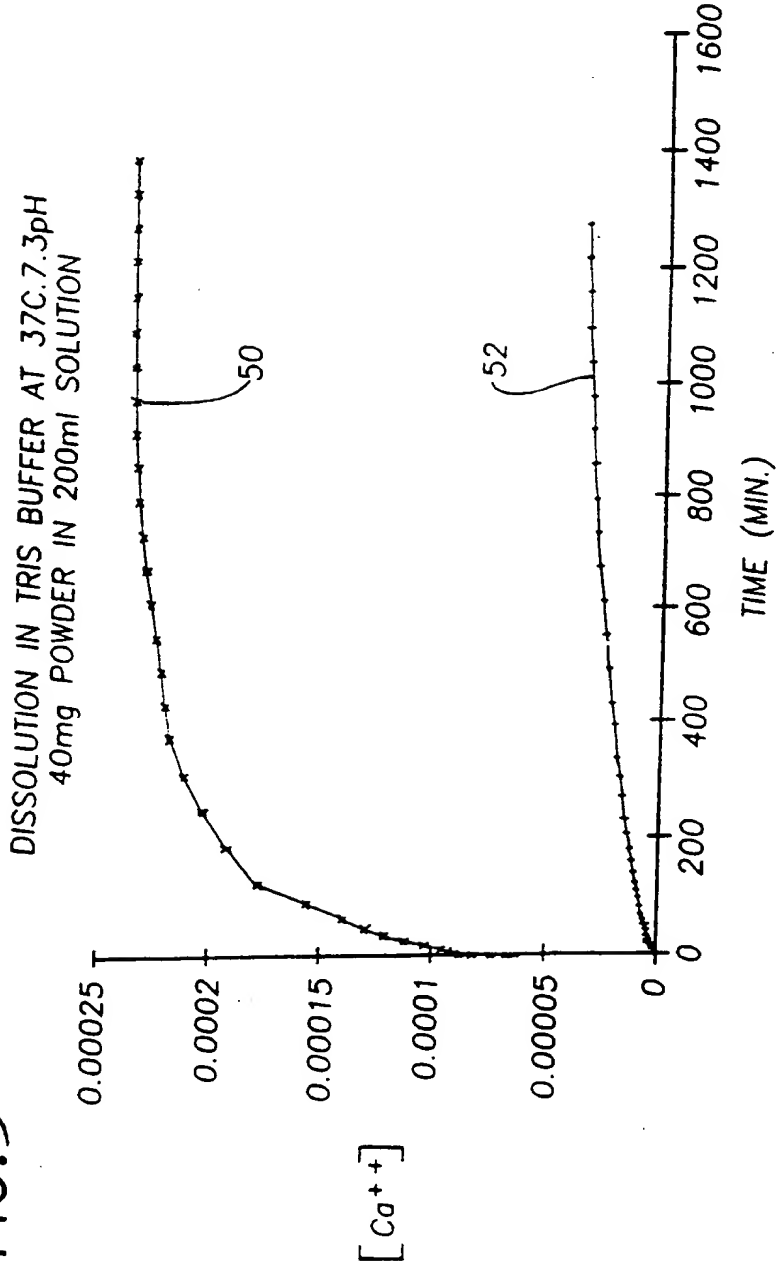

DISSOLUTION IN TRIS BUFFER AT 37C.7.3pH
40mg POWDER IN 200ml SOLUTION
50
52
0.00025
0.0002
0.00015
0.0001
0.00005
0
[Ca++]
0
200
400
600
800
1000
1200
1400
1600
TIME (MIN.)

FIG. 3

FIG. 4

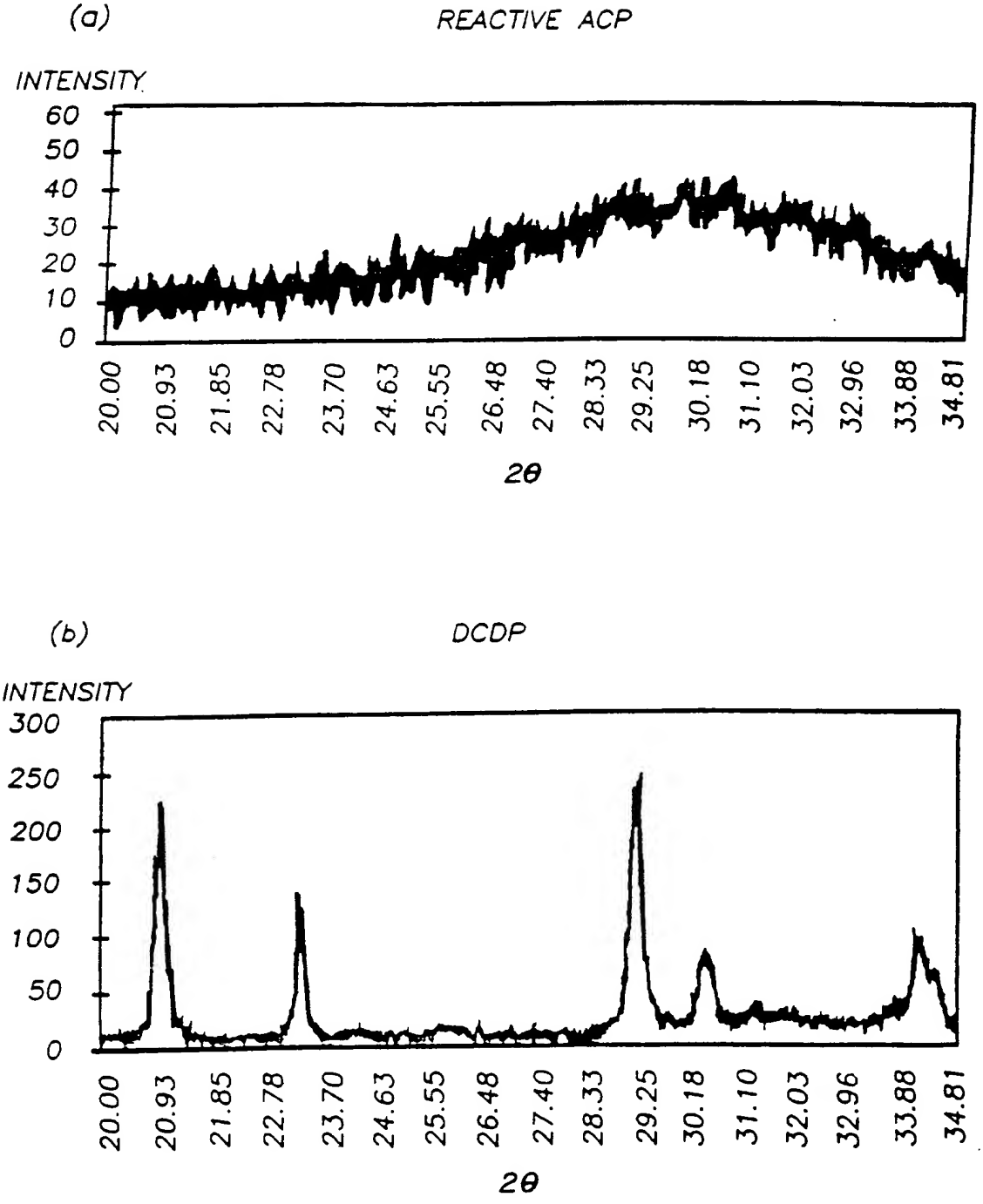

(a)
REACTIVE ACP
INTENSITY
60
50
40
30
20
10
0
20.00
20.93
21.85
22.78
23.70
24.63
25.55
26.48
27.40
28.33
29.25
30.18
31.10
32.03
32.96
33.88
34.81
2θ
(b)
DCDP
INTENSITY
300
250
200
150
100
50
0
20.00
20.93
21.85
22.78
23.70
24.63
25.55
26.48
27.40
28.33
29.25
30.18
31.10
32.03
32.96
33.88
34.81
2θ

FIG. 5

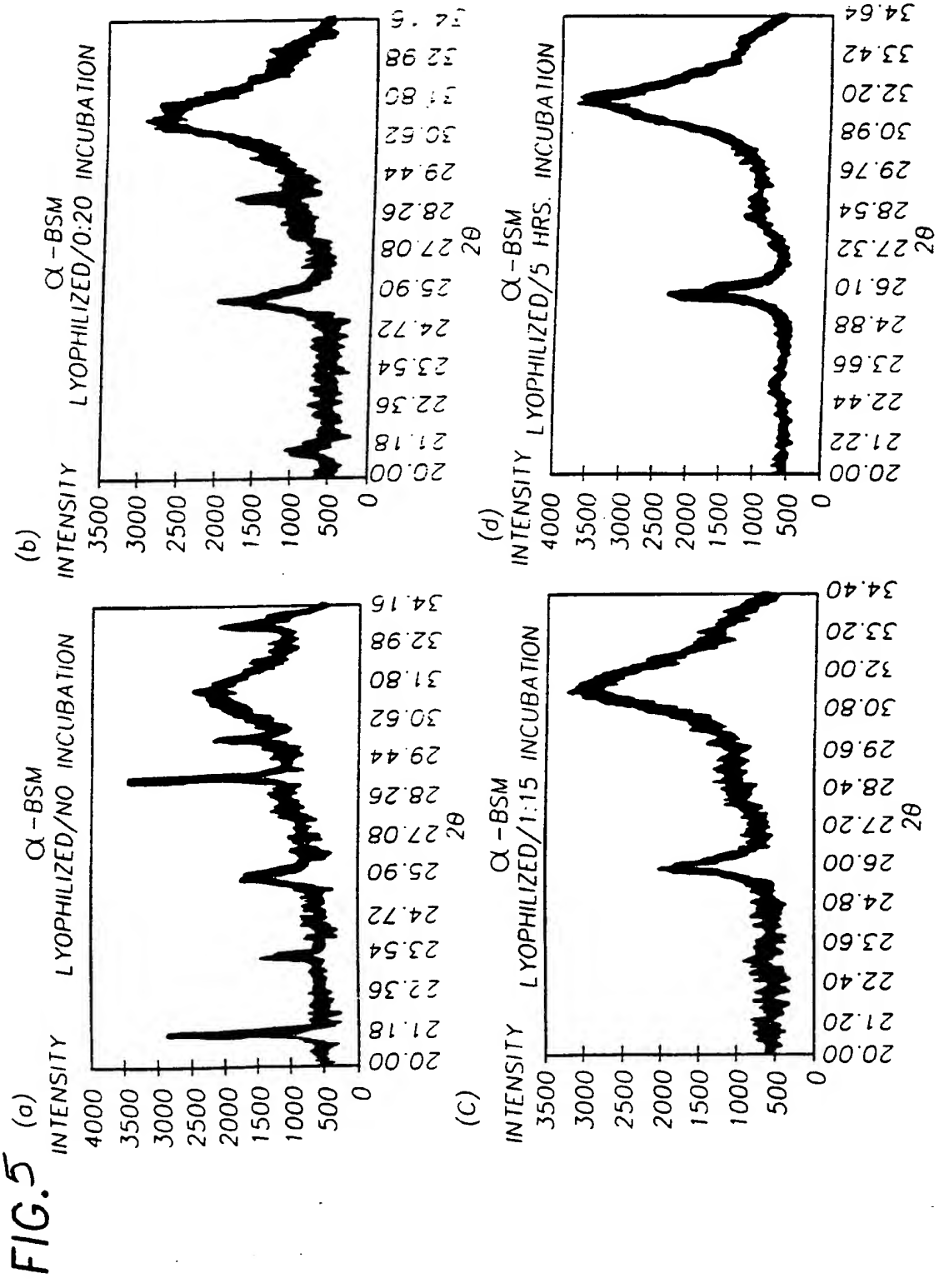
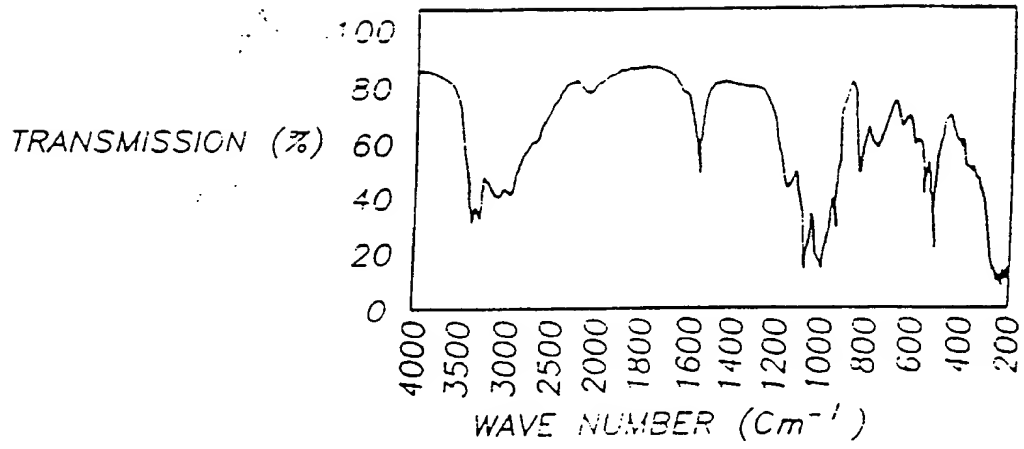
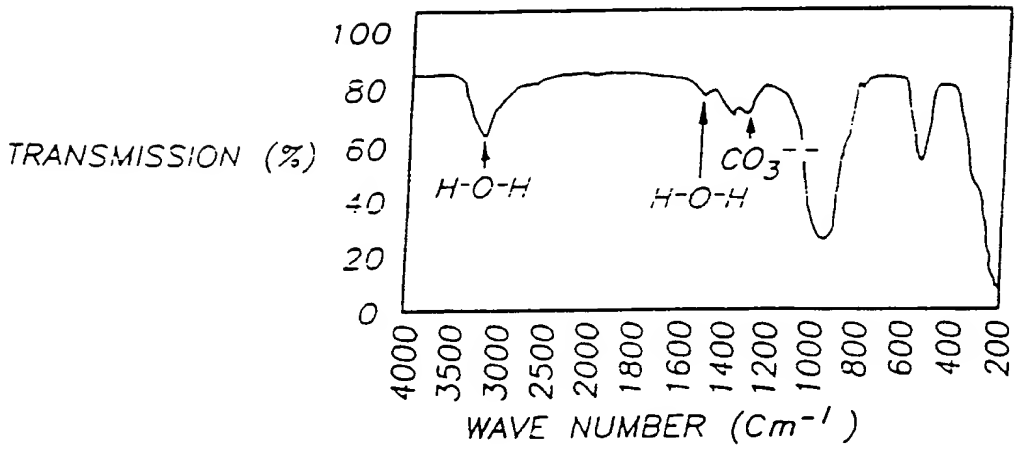


FIG. 6

(c)


TRANSMISSION (%)
100
80
60
40
20
0
4000 3500 3000 2500 2000 1800 1600 1400 1200 1000 800 600 400 200
WAVE NUMBER (Cm⁻¹)

(b)


TRANSMISSION (%)
100
80
60
40
20
0
H-O-H
H-O-H
CO3--
4000 3500 3000 2500 2000 1800 1600 1400 1200 1000 800 600 400 200
WAVE NUMBER (Cm⁻¹)

(C)

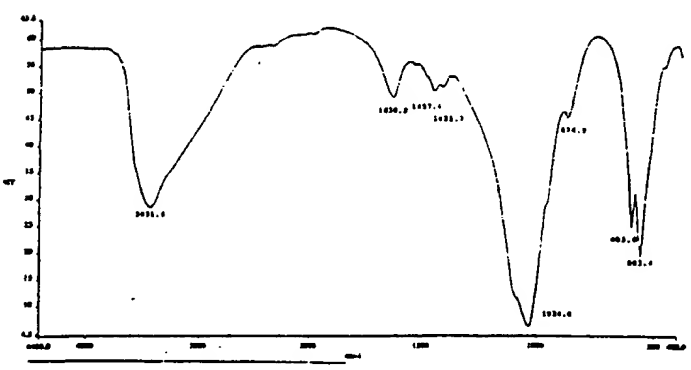
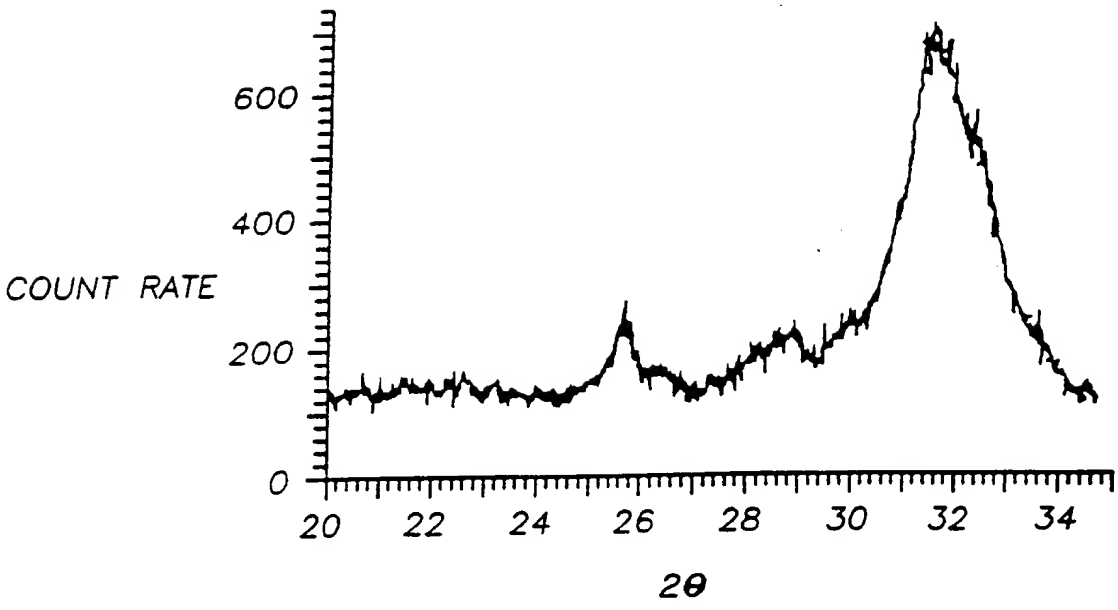


FIG. 7



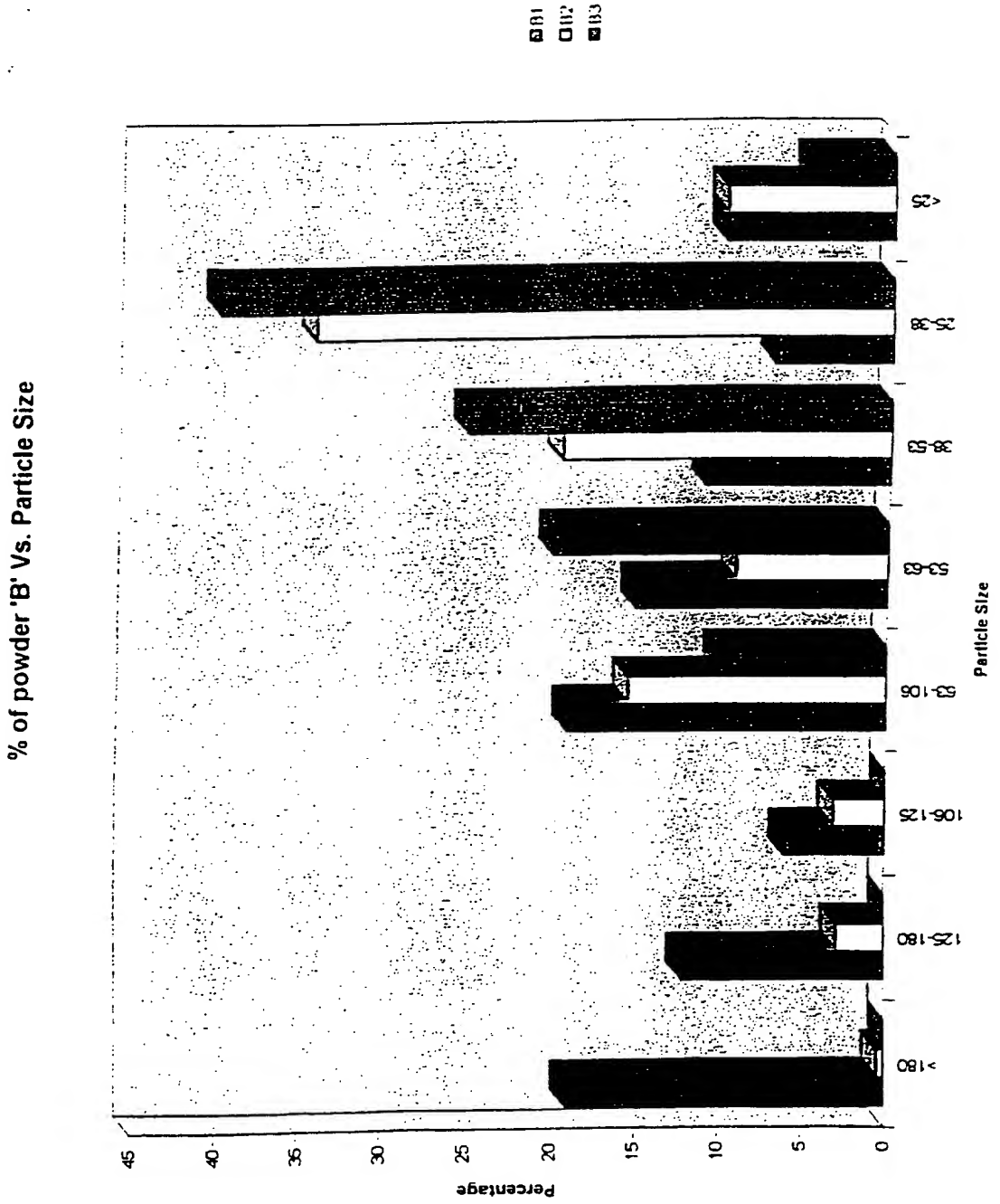


FIG 8

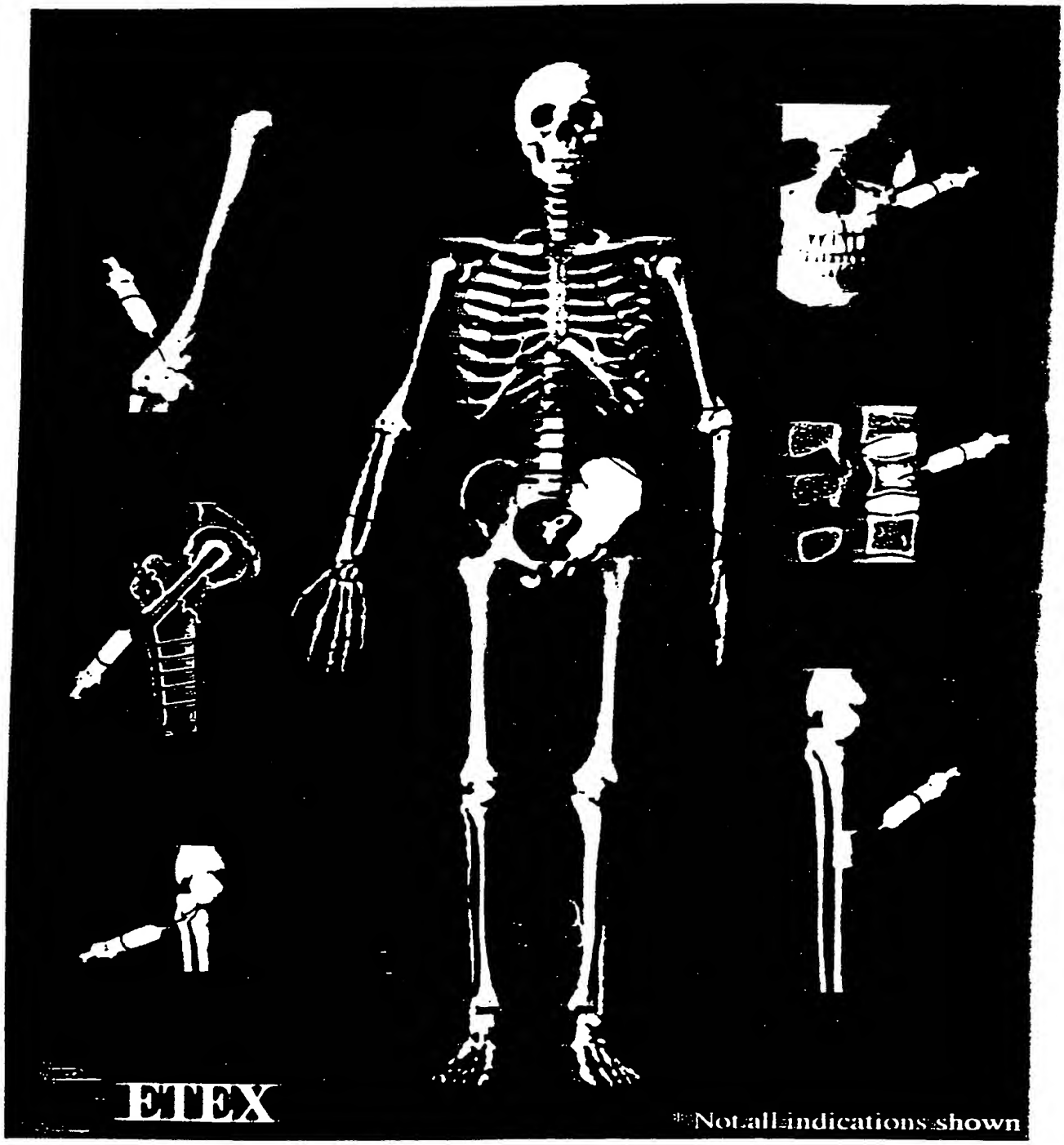


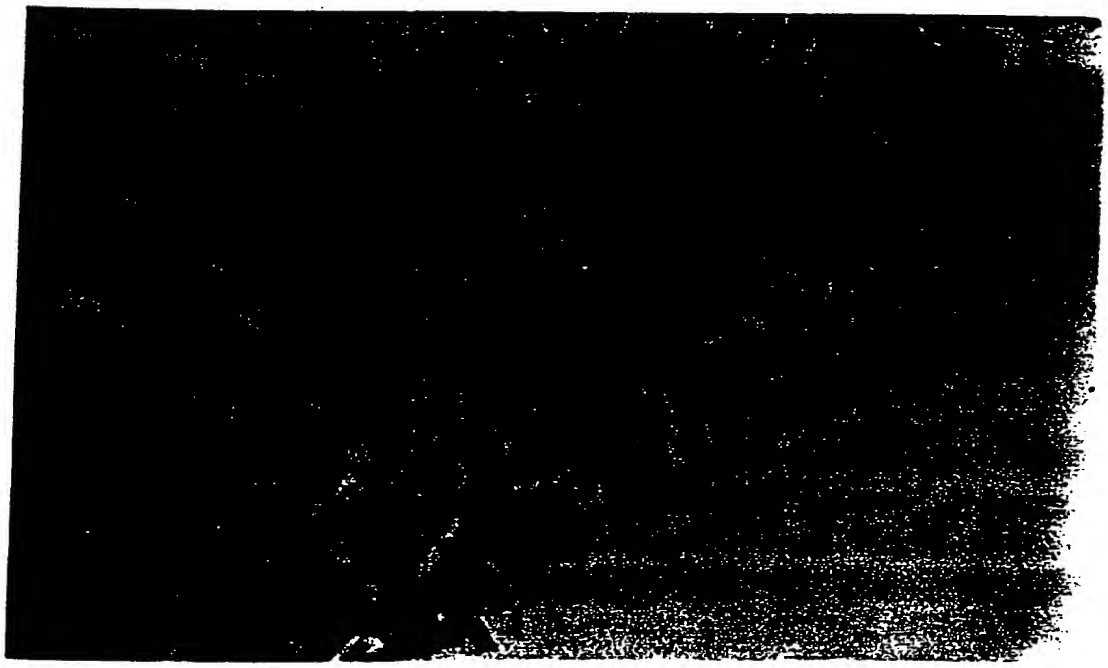
FIG 9

Study EX96-1-002
Bone Substitute Material (BSM™) Screening Assay in the NZW Rabbit Proximal Tibia Bone Defect Model

Photomicrograph of untreated control rabbit #73 tibia defect 2 weeks after surgery. The small arrows indicate one edge of the created defect. The large arrowhead is at the yet unbridged defect. Bone present to the right of the defect edge is in trabecular bone. Magnification 4x decalcified hematoxylin & eosin

Fig 10a

Study EX96-1-002
Bone Substitute Material (BSM™) Screening Assay in the NZW Rabbit Proximal Tibia Bone Defect Model



Photomicrograph of a bone defect treated with BSM from rabbit left 12 weeks after surgery. Large arrowheads denote the edge of the defect. New bone to the right of the defect edge is trabecular bone. Magnification 4X, decalcified, Hematoxylin and Eosin.

FIG. 10

Study EX95-1-004
Pilot Efficacy Study of Bone Substitute Material (BSM™) in the Canine Proximal Tibia Bone Defect Model

Photomicrograph of canine trabecular bone grown into the defect site treated with BSM. The small arrows denote osteoblast-like cells lining the bone spicules and are indicative of enhanced cellular activity. (Magnification 10X, decalcified, Hematoxylin & Eosin.

FIG. 11

Study EX95-1-004
Pilot Efficacy Study of Bone Substitute Material (BSM™) in the Canine Proximal Tibia Bone Defect Model

Photomicrograph of a canine cortical bone defect that was treated with BSM. The large arrows indicate one edge of the defect. The new bone growth is to the right of the defect and at 4 weeks after surgery is thick trabecular bone. (Magnification 4X, undecalcified, Light Green Basic Fuchsin)

FIG. 12

Study EX95-1-005
Establishment of a Bone Substitute Material (BSM™) Screening Assay in the NZW Rabbit Proximal Tibia Bone Defect Model

Photomicrograph of an untreated (control) tibia defect in rabbit #31 at 4 weeks after surgery. The large arrow indicates the edge of the defect. The small arrowheads indicate the remaining defect with no bone. Small arrows denote an abundance of fibrous connective tissue in the defect site. The large arrowhead points to new trabecular bone in the defect. (Magnification 4X, decalcified Masson's Trichrome)

FIG. 13a

Study EX95-1-005
Establishment of a Bone Substitute Material (BSM™) Screening Assay in the NZW Rabbit Proximal Tibia Bone Defect Model

Photomicrograph of a bone defect from rabbit #41 treated with BSM at 4 weeks after surgery. The large arrowheads demarcate the edge of the defect. The small arrows demarcate the intertrabecular bone growth into the defect site. Magnification of bone defect, hematoxylin & Eosin

FIG. 13b

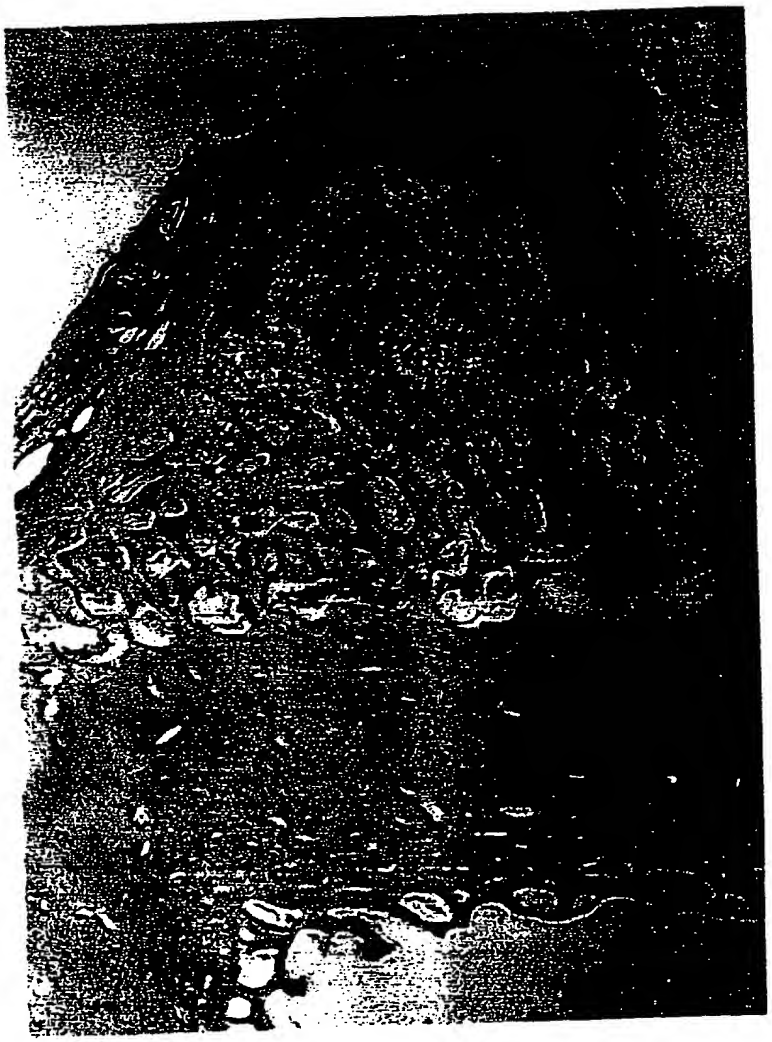


Fig. 14

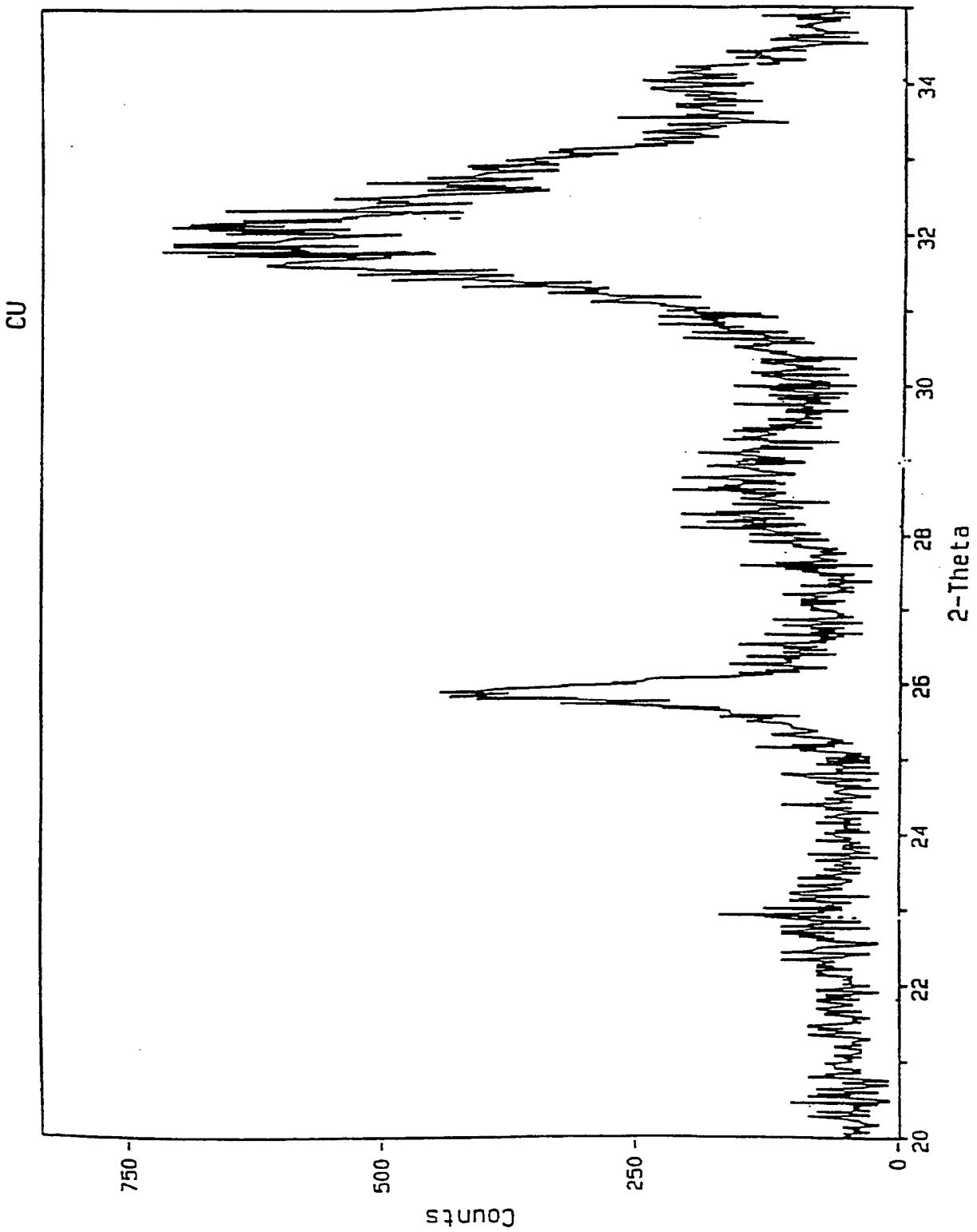


Figure 15

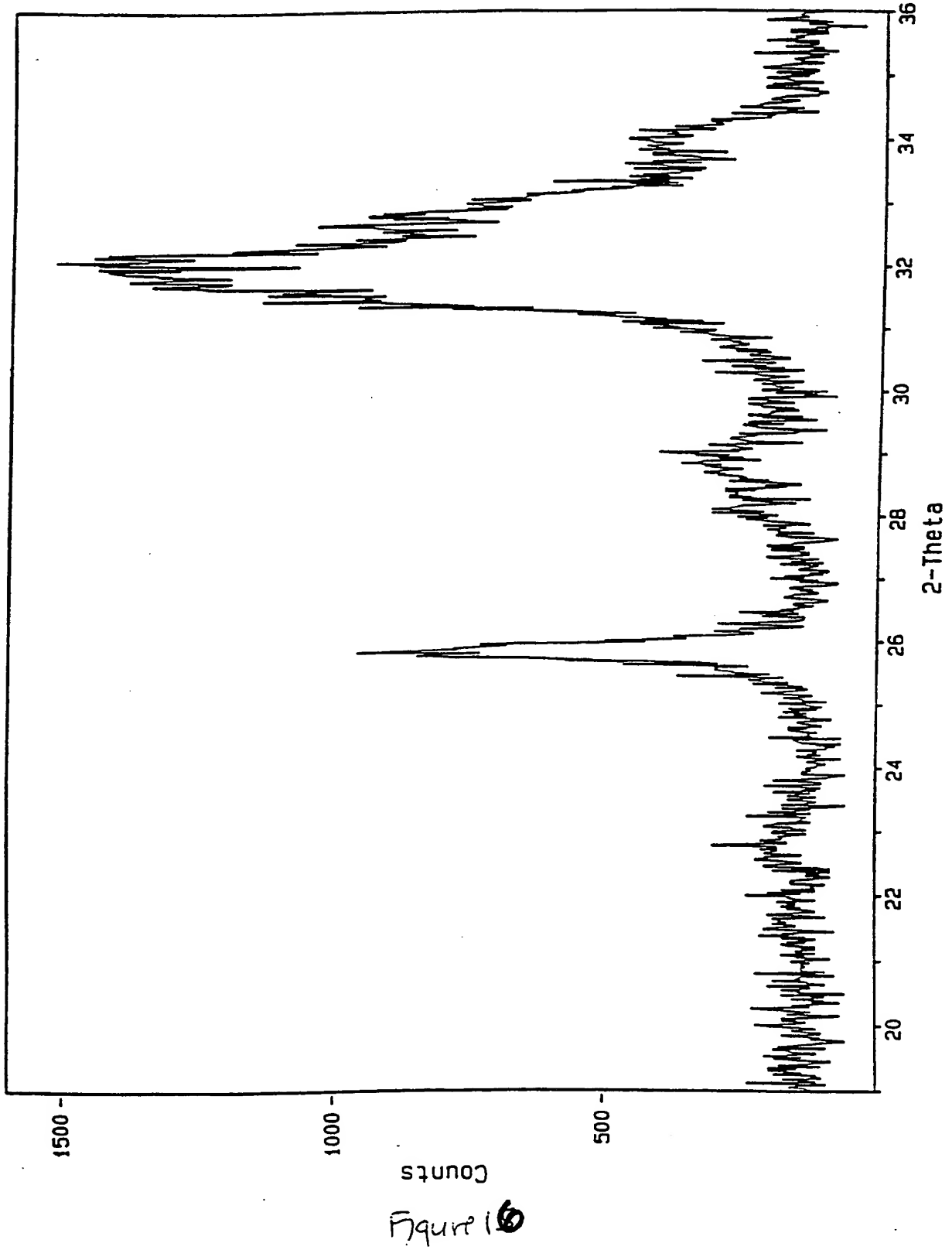


Figure 16

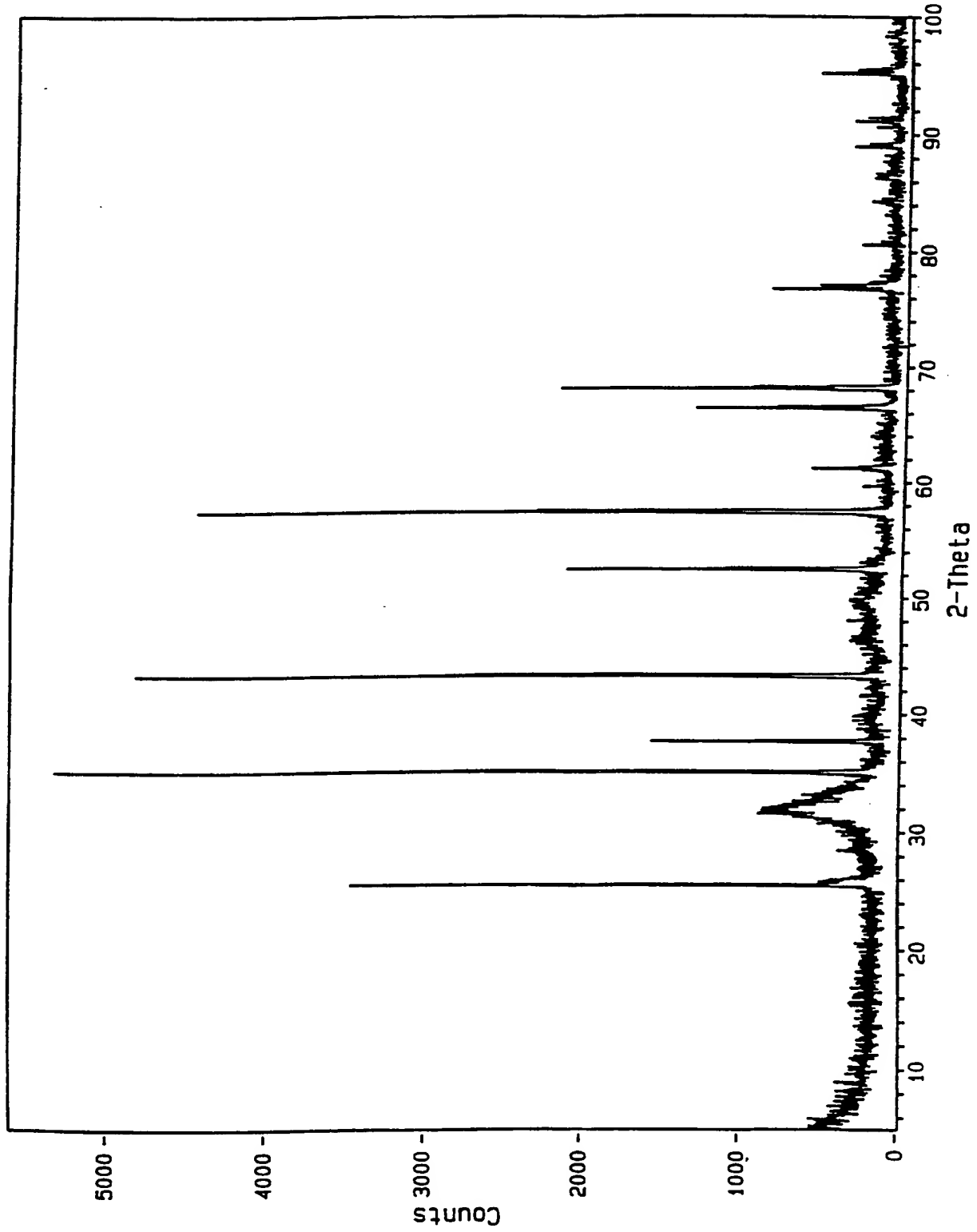
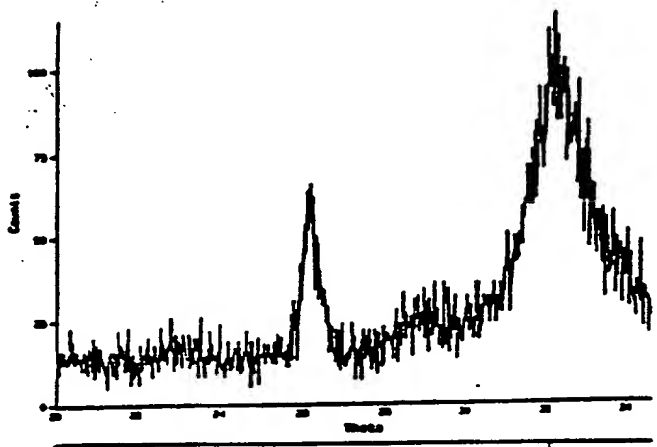

Counts
5000
4000
3000
2000
1000
0
2-Theta
10
20
30
40
50
60
70
80
90
100
cmse @ MIT

Figure 17

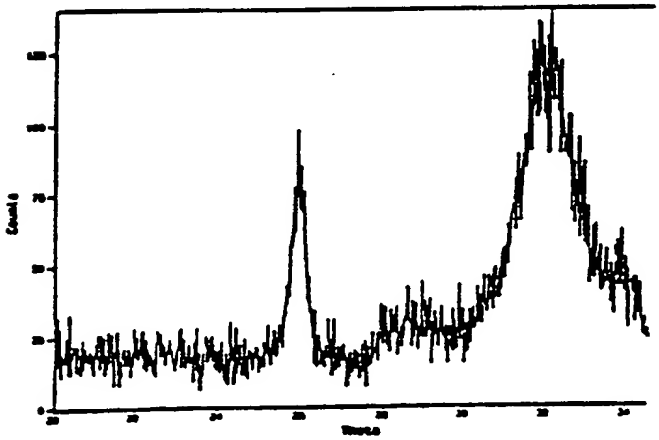
ETEX C . Confidential Report
Study 96-008

XRD ANALYSIS OF EXPLANTED α-BSM™ FOR DAYS 4,7,14

Panel 1



Panel 2



Panel 3

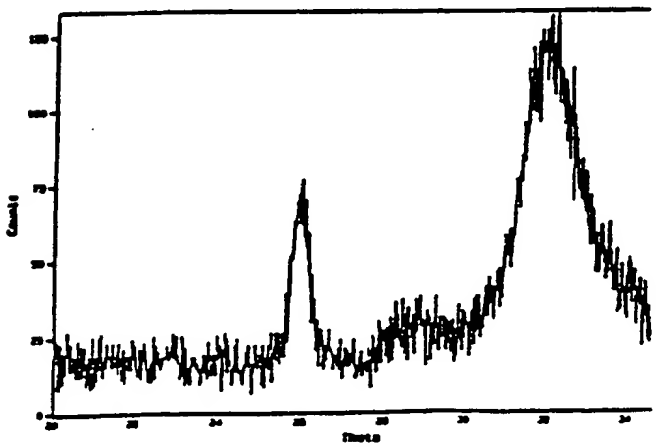
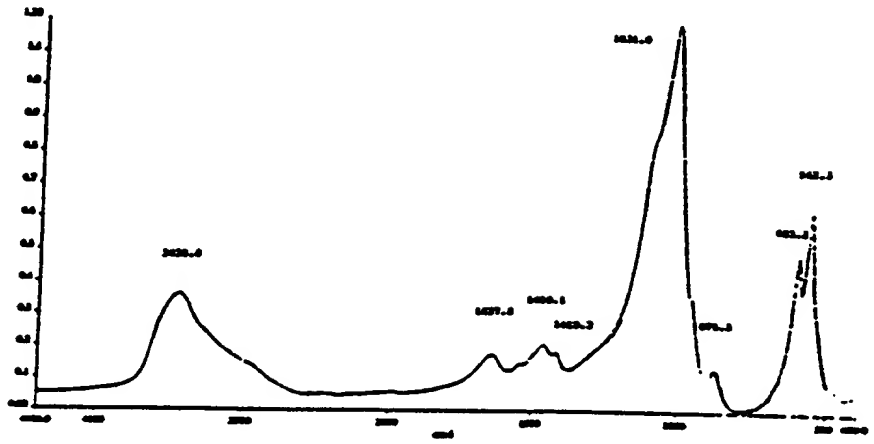


FIG 18

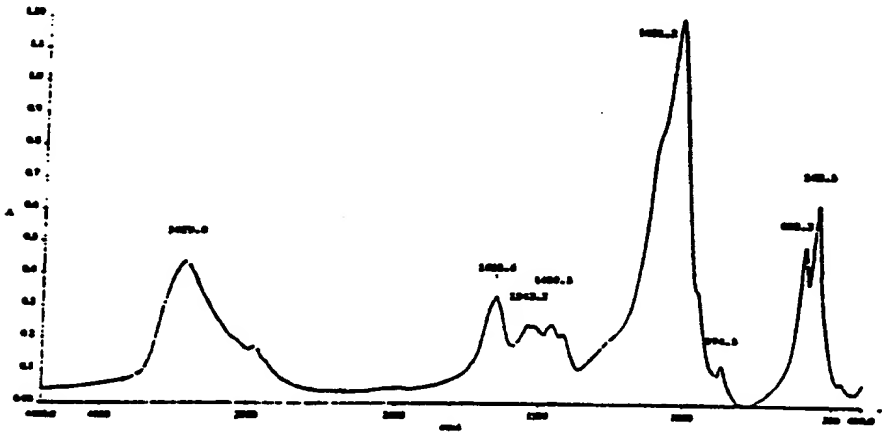
ETEX C ·. Confidential Report
Study 9o-..08

FTIR ANALYSIS OF EXPLANTED α-BSM™ FOR DAYS 4,7,14

Panel 1



Panel 2



Panel 3

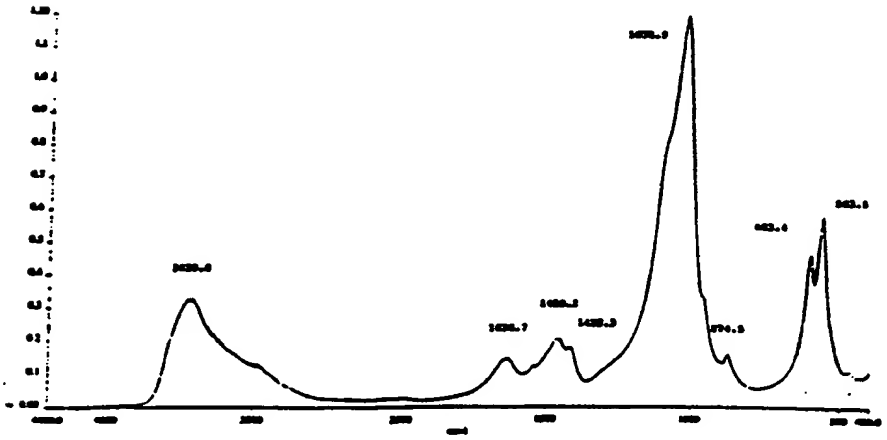
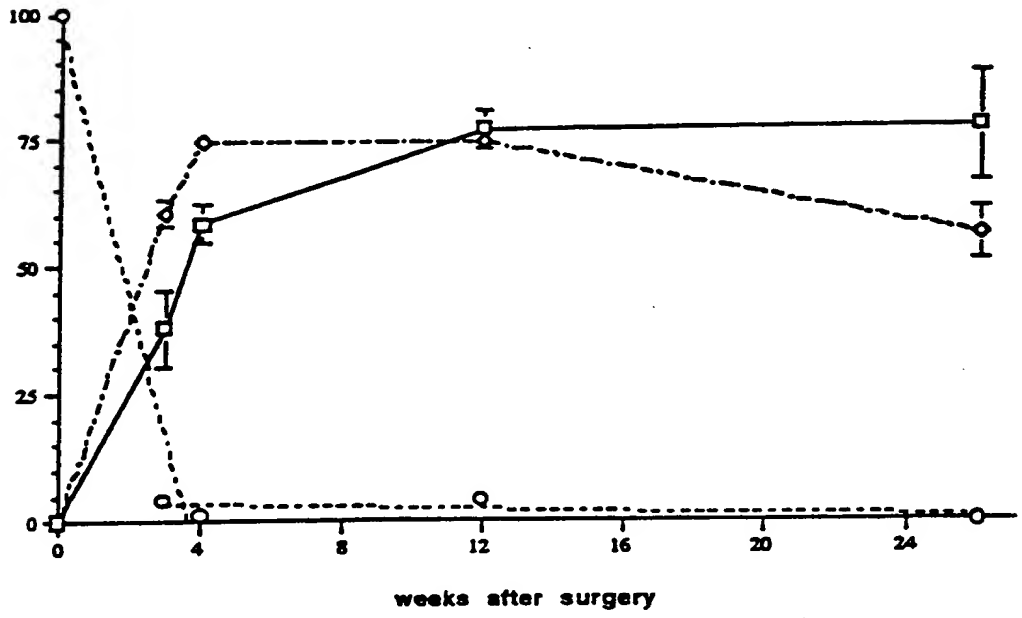


FIG 19

α-BSM™ Resorption and Defect Healing Compared to Autograft Healing



This figure demonstrates the resorption of α-BSM™ (circles) following implantation into a canine femoral defect. Also represented is the formation of new bone within the defect site, for animals treated with either α-BSM™ (squares) or with autologous bone (diamonds). The data is presented as the % of the defect occupied by calcium phosphate (either new bone or α-BSM™) as determined by light microscope histomorphometry of von Kossa stained undecalcified sections. Error bars represent standard error of the mean. For weeks 3 and 26, n=4; For weeks 4 and 12, n=8

FIG 20